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| **To:** | Examiner Abigail M. Cotton |
| **Fax #:** | (571) 273-8300 |
| **From:** | Thomas T. Aquilla |
| **Date:** | July 24, 2006 |
| **Subject:** | Ser. No. 10/826,098 Office Action Response |

TOTAL NUMBER OF PAGES, INCLUDING COVER: 4

**Comments:**

Faxed with this cover sheet is the following:

**Office Action Reply for 10/826,098 (3 pp.)**

**NOTE: In response to the Office Action mailed July 13, 2006, Applicant hereby submits a clean copy of the 131 Declaration filed on June 16, 2006.**

**CERTIFICATE OF FACSIMILE TRANSMISSION**

**FACSIMILE NO:** 1 (571) 273-8300 **DATE:** July 24, 2006

I hereby certify that this correspondence is being transmitted via facsimile to the Commissioner for Patents, Alexandria, VA 22313, to the facsimile number and on the date indicated above.

Thomas T. Aquilla

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

June 14, 2006

| | |
|---|---|
| In re Application of: | Tan *et al.* |
| Serial No. | 10/826,098 |
| Filed: | April 16, 2004 |
| For: | PHARMACEUTICAL COMPOSITIONS |
| Examiner: | Cotton, Abigail Manda |
| Art Unit: | 1617 |
| Attorney Docket No.: | DIZ-5 |
| Confirmation No.: | 9265 |

## DECLARATION OF PRIOR INVENTION IN A WTO MEMBER COUNTRY TO OVERCOME CITED PATENT OR PUBLICATION UNDER 37 CFR 1.131

MAIL STOP: AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

## PURPOSE OF DECLARATION

This declaration is being made by all of the inventors in the present application: Ma. Teresa Y. Tan, Eulogio Singh, Rita Josefina M. Santos and Kennie U. Dee. The purpose of this declaration is to establish a date of conception prior to the international filing date of Khan *et al.* (WO 02/43701 A1), cited by the Examiner in the Final Office Action dated November 17, 2005, coupled with due diligence from the conception date to the filing of the application in the United States Patent and Trademark Office. The international filing date of Khan *et al.* (WO 02/43701 A1) is December 1, 2000.

## FACTS

We, the undersigned inventors, do hereby declare and state as follows:

1. We are the joint inventors of the present invention, disclosed and claimed in U.S. Patent Application Ser. No. 10/826,098, filed April 16, 2004, entitled "PHARMACEUTICAL COMPOSITIONS".

2. Prior to December 1, 2000, the international filing date of the cited Khan reference, we conceived our invention as described and claimed in the above-identified application. Attached hereto as Exhibit A is a true and correct copy of actual entries made in our product development file. From this document it can bee seen that the invention was

conceived at least as early as April 28, 2000. Due diligence was exhibited from April 28, 2000 to April 16, 2004, when the present application was filed in the United States Patent and Trademark Office, claiming priority from our earlier-filed Philippines application.

3. All work and associated writings were carried out in the Philippines, which has been a member country of the WTO since January 1, 1995. Furthermore, the date of April 28, 2000, the date of conception of the invention, complies with the condition under 35 CFR 1.131(a) as amended, that the date of completion in a WTO country, other than a NAFTA member country, must fall on or after January 1, 1996.

4. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Ma. Teresa Y. Tan — Date: 6/15/06

Eulogio Singh — Date: 6/15/06

Rita Josefina M. Santos — Date: 6/15/06

Kennie U. Dee — Date: 6/15/06

# EXHIBIT A



Name : Cefuroxime Axetil
Innovator : Glaxo
Format : Tablet 125/250/500 mg , Suspension 125/250 mg
RM Suppliers : Accord, bpC, Ranbaxy, Aurobindo

## MARKET DATA (IMS)*

| 1998 sales | 1999 sales | Growth |
|---|---|---|
| P 494,350,375 | P 560,022,765 | 13% |

** includes sodium Cefuroxime injection*

## PRELIMINARY COSTING

| Format | Innovator | Unilab 30% COG | Unilab 40% COG |
|---|---|---|---|
| Tablet | P 57/ 250 mg | P 63.30 | P 47.48 |
| Suspension | P 300/50 ml (125 mg) | NA | NA |

## PATENT STATUS

| Patent | Remark | Patent Expiry |
|---|---|---|
| Axetil | Ester derivatives | MY 12/31/2001 |
| Amorphous form and Process | Amorphous form is the bioavailable form | MY 12/31/2004<br>SG 7/15/2005 |
| Suspension | Composition patent: lipid coating for tastemasking | RP 1/29/2009<br>MY 7/31/2010<br>SG 8/23/2008 |
| Tablet | Composition patent: thin film coating for rapid release | RP 9/18/2008<br>MY 4/30/2009<br>SG 10/26/2007 |

## COMMENTS

Sodium Cefuroxime used in the injection format is poorly absorbed when used orally. Cefuroxime Axetil, an ester of Cefuroxime, is a prodrug with good bioavailability. The commercial Cefuroxime Axetil is in amorphous form. Composition patent for suspension can be circumvented by using non-lipid coating. First step is to look for supplier who can sell us non-infringing coated granules; if not available, develop locally. Composition patent for tablet is with thin film coating, can circumvent if we use capsule format or tablet without film coating, or tablet inside a capsule ?

4/28/2000

Maria Teresa B. Tan